STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050686	A. BUILDING _____ B. WING _____	08/28/2007

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KAISER FOUNDATION HOSPITAL, RIVERSIDE	10800 MAGNOLIA AVENUE, RIVERSIDE, CA 92505 RIVERSIDE COUNTY

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	E 000 Initial Comments The following reflects the findings of the California Department of Public Health during a Full Medicare survey. On August 23, 2007, at 5:22 PM, Immediate Jeopardy (IJ) was identified regarding the Pharmaceutical Services. The IJ was abated on August 23, 2007, at 6:40 PM. Representing the Department: [redacted], HFEN; [redacted], HFEN; [redacted], HFEN; [redacted], MD, Medical Consultant; [redacted], Pharmacy Consultant; [redacted], Pharmacy Consultant; [redacted], RD, Nutrition Consultant; and [redacted] RD, Nutrition Consultant The sample size for the IJ was seven. The sample size was 40 patients. A 012 1280.1(a) HSC Section 1280 If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation. A 014 1280.1 (c) HSC Section 1280			

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	Continued From page 1 For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. E 474 T22 DIV5 CH1 ART3-70263 (c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. E474 T22 DIV5 CH1 ART3-70263(c) Pharmaceutical Service General Requirements (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. Based on observation, staff interviews, document			

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	Continued From page 2 reviews, clinical record reviews, and policy and procedures reviews, the facility failed to protect patients from potential adverse medication consequences by failure to prescribe, administer and monitor the use of Droperidol (Inapsine) in accordance with manufacturer's specifications on safe use of the medication. Specifically the facility failed to; 1. Assess for clinical contraindications in two (2) of seven (7) patients (1 and 5) prior to ordering Droperidol as evidenced by a lack of a cardiac assessment 2. Monitor cardiac function during and after administration of Droperidol in one of seven patients (5) 3. Identify emergence of potential fatal arrhythmias 4. Ensure that patients with orders for administration of Droperidol were on clinical units with equipment to monitor cardiac function for emergence of a fatal arrhythmias in five (5) of seven (7) patients (1,2,3,4,5) and 5. Develop pre-printed medication order sheets that promoted the use of Droperidol consistent with the manufacturer's guidelines for safe administration of the medication. Findings: On 8/23/07 at 5:22 PM, the hospital administration staff was informed that Immediate Jeopardy (IJ) had been identified based on the hospital's failure to protect patients from potential undue adverse medication consequences from Droperidol (Inapsine). Patients receiving Droperidol (Inapsine)			

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	Continued From page 3 were not monitored for potential serious and life threatening cardiac arrhythmias (serious irregular heart beats) as required by the manufacturer's Black Box warning. The hospital was asked to provide a plan of correction to address the IJ. On 8/23/07 at 6:40 PM, a finalized plan of correction was submitted and accepted. The IJ was lifted on 8/23/07 at 6:40 PM. The director of pharmacy stated that Droperidol had been removed from floor stock on all Medical Surgical Units, Family Centered Care Unit, Critical Care floor units and the Emergency Room for patient use, and this was documented in their plan of correction. On 8/20/07 at 1:20 PM during a medication storage inspection conducted on 4E, a medical surgical unit/pediatric unit/Orthopedic, 10 vials of Droperidol (Inapsine) were found in the medication room. Droperidol is an antiemetic medication that carries a Black Box Warning to alert prescribers, dispensers and healthcare professionals who administer the medication that precautions must be taken to avoid serious adverse reactions in patients. These precautions include a baseline electrocardiogram and cardiac monitoring during and after administration of the medication. On 8/21/07 at approximately 3:10 PM, 9 vials of Droperidol 5mg/2ml were found in Post Anesthesia Care Unit (PACU) medication cart. Registered Nurse (RN) 3, the clinical manager asked MD A to explain how Droperidol is used in the unit. MD A stated that as a last resort, she would use Droperidol for refractory nausea/vomiting and at a dose of 0.625 mg.			

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	Continued From page 4 On 8/22/07 at approximately 9:46 AM to 10:10 AM, follow-up interviews conducted with RN1, RN 2, and Director of Pharmacy (DOP) revealed that Droperidol was available for patient use on 4 E, and had been used on the unit. RN 2 was unsure of when Droperidol had been prescribed for a patient on 4 E, but she stated that it could have been within the last two weeks. RN 1 and RN 2 were asked what information should be provided before Droperidol was administered to a patient, and if they had been aware of the Black Box Warnings (BBW). A black box warning is intended to alert practitioners to serious risks, particularly those that may lead to death or serious injury. RN 1 and RN 2 could not state that they were aware of the BBW or high risks associated with Droperidol's use. The Director of Pharmacy director (DOP) reported that Droperidol was allowed to remain on the medical surgical floor per an approved request from the Department of Anesthesiology. A review of the Pharmacy policies and procedures revealed that Droperidol, in various quantities, was available for use on the following patient care units: 5 W, Anesthesiology Main- OR, Anesthesiology OB-Workroom, Emergency Department - 1, Emergency Department - 2, Intensive Care Unit/Critical Care Unit (ICU/CCU), Labor & Delivery Unit, PACU, and PACU On-Call Cart. On 8/22/07 at approximately 2:15 PM to 2:35 PM three (3) physicians (B, C, and D), the Pharmacy & Therapeutics (P&T) chairperson and the Pharmacy Executive Director were interviewed regarding the			

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	Continued From page 5 use of Droperidol within the facility. All three physicians stated that they personally had not used Droperidol since the BBW issue came about, or seen it used in the facility within months to years. Physician D reported that a physician who is no longer at the facility used Droperidol about 5 years ago. On 8/22/07 at approximately 2 PM, the DOP provided documents from the Pharmacy and Therapeutics Committee minutes dated 3/27/02 confirming the decision to keep Droperidol on the formulary. When the surveyor requested a list of patients who were prescribed Droperidol in the last six months (March - August 2007), the DOP stated that it would be difficult to get that information because of the lack of an automated drug distribution system. During the pharmacy department review on 8/23/07 at 11:35 AM, the DOP provided the list of patients who were prescribed Droperidol at 6 PM on 8/22/07. The list consisted of 64 patients who were prescribed IV Droperidol March 24, 2007 through August 21, 2007. From that list, the surveyor selected seven patients and their clinical records reviewed. On 8/23/07 at 1:30 PM, a review of seven (7) clinical records revealed that five (5) of (7) patients (1, 2, 3, 4, 5) had not been monitored by means of a telemetry device for potential cardiac adverse events during and after administration of Droperidol. Further review revealed that an electrocardiogram (ECG) had not been ordered for Patient 1 and 5			

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	Continued From page 6 prior to an order for Droperidol as specified in the manufacturer ' s black box warning for assessment of clinical contraindications. A review of Preprinted order sheets on 8/23/07 entitled, " Radical Prostatectomy Post-Op Doctors Orders ", " Adult Standard Admission Orders ", and " Post Anesthesia Care Unit (PACU) Doctors Orders "for Patients 2, 5 and 6 respectively, listed Droperidol (Inapsine) as a medication choice for the treatment of nausea/vomiting without indicating that it is a high risk drug or including recommendations that other drugs should be used first. Record reviews revealed that Patient 5 received IV Droperidol on a non- telemetry unit on the following dates and times: Patient 5 had a physician's order for Droperidol 1.25 milligrams IV (intravenous) q6h (every six hours) PRN (as needed) N/V (nausea/vomiting). Patient 5 received 6 doses on 3 W on 3/25/07 at 2:05 AM, 8:30 AM, on 3/28/07 at 3:20 AM, and on 3/31/07 at 4:05 AM, 1:35 PM and 9:35 PM. The corrected QT reported 3/31/07 at 2:17 PM was 517 milliseconds (msec), greater than 440 msec which is indicative of a prolonged QT interval. Droperidol (a medication indicated for nausea and vomiting) has a black box warning from the manufacturer. The black box warning states, "Cases of QT prolongation and/or torsades de pointes have been reported in patients receiving Droperidol at doses at or below recommended doses. Some cases have occurred in patients with no known risk factors for QT prolongation and some			

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	Continued From page 7 cases have been fatal. Due to its potential for serious proarrhythmic effects and death, Inapsine (Droperidol) should be reserved for use in the treatment of patients who fail to show an acceptable response to other adequate treatments, either because of insufficient effectiveness or the inability to achieve an effective dose due to intolerable adverse effects from those drugs. Cases of QT prolongation and serious arrhythmias (e.g., torsades de pointes) have been reported in patients treated with Droperidol. Based on these reports, all patients should undergo a 12-lead ECG prior to administration of Inapsine (Droperidol) to determine if a prolonged QT interval (i.e., QTc greater than 440 msec for males or 450 msec for females) is present. If there is a prolonged QT interval, Inapsine (Droperidol) should NOT be administered. For patients in whom the potential benefit of Inapsine (Droperidol) treatment is felt to outweigh the risks of potentially serious arrhythmias, ECG monitoring should be performed prior to treatment and continued for 2-3 hours after completing treatment to monitor for arrhythmias. " Additionally the manufacturer lists the only indication for use is to reduce the incidence of nausea and vomiting associated with surgical and diagnostic procedures. Torsades de Pointes is a cardiac arrhythmia, which may cause blackouts or sudden death. The QT interval represents the duration of ventricular depolarization and subsequent repolarization, a delay in cardiac repolarization creates an electrophysiological environment that favors the development of cardiac arrhythmias,			

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	Continued From page 8 most clearly torsade de pointes (TdP), but possibly other ventricular tachyarrhythmias as well. Because of its inverse relationship to heart rate, the measured QT interval is routinely corrected by means of various formulas to a less heart rate dependent value known as the QTc interval. According to the Federal Food and Drug Administration (FDA) MedWatch Program a "Dear Health Care Professional "letter was sent out by the manufacturer of Droperidol on December 4, 2001. The letter was to warn all healthcare professionals about the potential of serious and fatal arrhythmias associated with the use of the medication. The exact language of the warning sent was the language printed in the manufacturer's black box labeling information. The information regarding the Black Box Warning had been made available more than four years ago to all facilities, including all of their health care professional staff (e.g. pharmacists, physicians and nurses), regarding life threatening arrhythmias associated with Droperidol and the restriction of its use as a second line agent in the treatment of perioperative nausea and vomiting by the manufacturer. In spite of this widely known information the facility failed to revise their preprinted order sets to promote safe use of Droperidol consistent with manufacturer and FDA guidance. There was no documentation on the preprinted order sheet that Droperidol (Inapsine) was a high			

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	Continued From page 9 risk drug and there were no guidelines listed for monitoring for adverse consequences. There were no recommendations that other drugs should be used first for nausea as recommended with the manufacturer's specifications/warnings.			

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